K080224

JUL - 3 2008

PREMARKED NOTIFICATION
[510 (K)] SUMMARY

1. IDENTIFICATION

2. DEVICE NAME

3. PREDICATE DEVICE

4. DESCRIPTION

5. INTENDED USE

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

K080224

1. IDENTIFICATION

- *Denomination:* **KLOCKNER dental implants**

- *Manufacturer name and address:* **SOADCO, S.L.**
Avgda. Fiter i Rossell, 4bis – Local 2
ESCALDES - ENGORDANY
AD-700 (ANDORRA)

- *Contact person:* **Maria Mitjaneta**

- *Telephone and Fax numbers:* **(376) 800 590** / Fax- **(376) 800 594**

- *Date:* **06/03/08**

2. DEVICE NAME

TRADE NAME: KLOCKNER essential dental implants system models Essential Cone (EC), Essential Solid (ES), ECK.

COMMON NAME: Dental endosseous implant

CLASSIFICATION NAME: Endosseous implant (21 CFR 872.3640)
Endosseous dental implant abutment (21 CFR 872.3630)

3. PREDICATE DEVICE / LEGALLY MARKETED DEVICE

NAME: Dental endosseous implant

LEGALLY MARKETED DEVICE:

Klockner dental implants models S3M (K052654) SK2, NK2, S4, S6 (K010132)
Straumann RN Dental implants (K033922) (K030007) (K07188) (K062129) (K041295) (K070549) (K962023) (K071585) (K994119) (K063789) (K033243)
3i Dental Implants (K030614) (K072363)

4. DESCRIPTION

The Klockner Essential implant system consists of a group of implants, implant accessories and additional material to restore the mastication system. The different EC, ES and ECK models are available in three different diameters: 3.5mm, 4.0mm and 4.8mm and the range of lengths varies between 8mm and 16mm. They are internally connected.

5. INTENDED USE OF THE DEVICE

The Klockner Essential implant system is especially designed for surgical insertion into the bone using additional material to replace the root of the teeth, acting as the support for the dental implants formed by implant accessories.

The Essential Solid implants are fitted with an internal octagonal conical connection combined with an external octagonal connection measuring 1.2 mm in height.

The Essential Cone implants are fitted with an internal octagonal conical connection. **The Essential ECK implants are fitted with** a larger internal octagonal conical connection than that of the Essential Cone implants.

Immediate loading is appropriate for the Essential Solid, Essential Cone and Essential ECK implants when good primary stability is achieved with appropriate occlusal loading.

Indications:

· The 3.5mm Ø **ESSENTIAL® implants** are recommended for fitting in hard or compact bones [D1-D2 bone type], such as the lower jaw.

· The 4.0mm Ø **ESSENTIAL® implants** are recommended for fitting in soft or cancellous bones [D3-D4 bone type], such as the upper maxillary.

· The 4.8mm Ø **ESSENTIAL® implants** are recommended for the replacement of molars and for fitting immediate implants.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The subject implants and abutments are substantially equivalent to the previously cleared Klockner dental implants system cleared in K010132 and K052654 because the intended use, the composition and the endosseous surface treatment are identical to the Klockner predicate devices. The design principles are the same as the Klockner predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 8 2008

Ms. Maria Mitjaneta
Quality Assurance Manager
SOADCO, S.L.
Avgda, Fiter I Rossell
4 Bis Local 2
Escaldes-Engordany
ANDORRA AD - 700

Re: K080224
Trade/Device Name: Klockner Essential Implant System Models Essential Cone (EC), Essential Solid (ES), ECK
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: June 3, 2008
Received: June 6, 2008

Dear Ms. Mitjaneta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080224

510(k) Number (if known): K080224

Device Name: KLOCKNER ESSENTIAL IMPLANT SYSTEM MODELS ESSENTIAL CONE (EC), ESSENTIAL SOLID (ES), ECK

Indications For Use:

The Klockner Essential implant system is especially designed for surgical insertion into the bone using additional material to replace the root of the teeth, acting as the support for the dental implants formed by implant accessories.
The Essential Solid implants are fitted with an internal octagonal conical connection combined with an external octagonal connection measuring 1.2 mm in height.
The Essential Cone implants are fitted with an internal octagonal conical connection.
The Essential ECK implants are fitted with a larger internal octagonal conical connection than that of the Essential Cone implants.
Immediate loading is appropriate for the Essential Solid, Essential Cone and Essential ECK implants when good primary stability is achieved with appropriate occlusal loading.
Abutments can be used in single tooth replacements and multiple tooth restorations.
8mm Implants are not indicated for use as unitary implants and for immediate load.

Prescription Use X **OR** **Over-The-Counter Use**
(Per 21 CFR 801.109)

Robert DDS for Dr. Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080224